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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,860	07/24/2001	Kanji Nakamura	9659/OL377US0	4215

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EXAMINER
RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
1652	11

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/911,860	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 July 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Claims 1-20 are pending.

It is noted that the examination of the instant application has been assigned to a different Examiner in Group Art Unit 1652.

Applicant's election without traverse of SEQ ID NO: 3 and Group I, claims 1-4 drawn in part to a nucleic acid and a labeled probe, in Paper No. 10, filed on 5/30/2003 is acknowledged.

Applicants submit that since claims 1-4 are generic, upon allowance of a claim directed to the elected species, they are entitled to consideration of claims to additional species. It is noted, however, that the restriction requirement did not include an election of species. As indicated in previous Office Action Paper No. 9, Groups a-o, corresponding to SEQ ID NO: 1-15, are considered patentable distinct inventions (paragraph 6). Furthermore, the previous Office Action clearly stated the reasons why the claimed polynucleotides are independent and patentably distinct inventions and why the search of all of them would impose an undue burden on the Examiner (paragraph 9). Therefore, no additional polynucleotides will be considered for examination in the instant application.

The requirement is deemed proper and therefore is made FINAL.

Claims 5-20 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

It is noted that some of the elected claims are still partially drawn to non-elected inventions. Examination of such claims will be restricted to the subject matter elected, which in

the instant case is the polynucleotide of SEQ ID NO: 3. Applicants are requested to amend the claims accordingly in response to this Office Action.

Priority

1. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. 119(a)-(d) to JAPAN 2000-227580 filed on 07/24/2000, and JAPAN 2001-066001 03/09/2001.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11/7/2002 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

3. The drawings have been reviewed and are approved by a draftsperson under 37 CFR 1.84 or 1.152.

Claim Objections

4. Claims 1-4 are objected to because they are partially drawn to non-elected inventions, i.e. Groups a-o. For examination purposes, the claims will be interpreted as being drawn solely to the elected polynucleotide of SEQ ID NO: 3. Appropriate correction is required.

5. Claims 1-2 are objected to because of the recitation of "18~25" and "10~50". For examination purposes, the terms will be interpreted as "18 to 25" and "10 to 50", respectively. It

is noted that claim 1 should be amended to recite "18 nucleotides" instead of "18 to 25" since SEQ ID NO: 3 only contains 18 nucleotides. In regard to claim 2, since SEQ ID NO: 3 only contains 18 nucleotides, the term "10~50" should be "10 to 18". Appropriate correction is required.

6. Claim 1 is objected to due to the recitation of "a base sequence of SEQ ID NO: 1". For clarity, it is suggested that the term be amended to recite "the base sequence of SEQ ID NO: 1" since the sequence has been defined by its sequence identifier. Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-2, as written, do not sufficiently distinguish over 16S RNAs and encoding nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 US 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "an isolated" or "a purified" as taught by page 6, lines 11-15, of the specification. See MPEP 2105.

Claim Rejections - 35 USC § 112, Second Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 1 and 2 (claim 3-4 dependent thereon) are indefinite in the recitation of "nucleic acid ..has a base sequence selected from the group consisting of ....a base sequence complementary to said base sequence of .." for the following reasons. First, the term "complementary" is indefinite since it is unclear which "complements" are encompassed by the claim. Fragments of any size which are complementary to the polynucleotide claimed can be considered as "complements". Applicants have not define the term "complement", as it relates to size, in the specification either. If applicants wish to claim the entire complement, it is suggested that the term "complementary" be replaced with "completely complementary". Correction is required.

12. Claims 1 and 2 are indefinite in the recitation of "nucleic acid....which preferentially hybridizes to at least one of the 16S rRNA and the rDNA" since it is unclear as to whether the nucleic acid should preferentially hybridize to both the 16S rRNA and the rDNA or whether it should hybridize to either the 16S rRNA or the rDNA. For examination purposes, it will be assumed that the claim recites "nucleic acid ...which preferentially hybridizes to at least the 16S rRNA or the rDNA..". Correction is required.

13. Claim 2 is indefinite in the recitation of "nucleic acid comprising 10~50 nucleotides...wherein a base sequence of at least 10 individual bases in succession has a base sequence selected from the group consisting of (d)...and (e)..." for the following reasons. As written, it is unclear as to how the 10 base sequence is related to the nucleic acid. In addition, it is unclear as to what (a), (b) and (c) are. For examination purposes, the claim will be interpreted as "an isolated nucleic acid comprising 10 to 50 nucleotides ....wherein said nucleic acid comprises at least 10 consecutive bases of a polynucleotide selected from the group consisting of (a) the polynucleotide of SEQ ID NO: 3", and (b) the complete complement of the polynucleotide of (a)". Correction is required.

14. Claims 3 and 4 are indefinite in the recitation of "which is labeled by at least one of a radioactive element....., and chemical substance" for the following reasons. As written, it is unclear if the probe should be labeled by each one of the compounds recited or by at least one of the compounds recited. It is suggested that if the probe should be labeled by at least one of the compounds recited, the claims be amended to recite "which is labeled by at least one radioactive element, enzyme....or chemical substance". For examination purposes, the suggested language will be used. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 3 are drawn to a genus of nucleic acids of any function comprising the 18-base polynucleotide of SEQ ID NO: 3 or a 90% sequence homolog of the polynucleotide of SEQ ID NO: 3. Claims 2 and 4 are drawn to a genus of nucleic acids of any function comprising at least 10 bases of the polynucleotide of SEQ ID NO: 3. See claim rejections under 35 USC 112, second paragraph for claim interpretation. While the specification discloses the structure of the polynucleotide of SEQ ID NO: 3 and its function as a probe to detect chlorinated ethylene-decomposing bacteria, no disclosure of the structures of other nucleic acids comprising the polynucleotide of SEQ ID NO: 3 has been provided, nor there is disclosure of other functions for such genus of polynucleotides. Furthermore, there is no disclosure of which 10 nucleotides of SEQ ID NO: 3 are essential to isolate chlorinated ethylene-decomposing bacteria or which bases in the polynucleotide of SEQ ID NO: 3 can be deleted, substituted or added to create a 90% structural homolog of the polynucleotide of SEQ ID NO: 3 and still retain the ability to detect chlorinated ethylene-decomposing bacteria.

Adequate written description of a genus of nucleic acids would have relevant identifying characteristics which include (1) structure, (2) physical and/or chemical characteristics, (3) functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) a combination of identifying characteristics sufficient to show that Applicant

was in possession of the claimed genus. In the instant case, the only structure disclosed is that of SEQ ID NO: 3 and the only function disclosed, i.e. detection of chlorinated ethylene-decomposing bacteria, is only relevant to 18 nucleotides (i.e. SEQ ID NO: 3). The genus of nucleic acids claimed is a large variable genus with the potentiality of encoding many different proteins. Many structurally distinct nucleic acids are encompassed within the scope of these claims. The specification only discloses one single species of the claimed genus which is insufficient to put one of ordinary skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at the USPTO website.

17. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 3, does not reasonably provide enablement for any polynucleotide of any function comprising (1) the polynucleotide of SEQ ID NO: 3 or (2) at least 10 nucleotides of the polynucleotide of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the

invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breath of the claims.

The scope of the claims, as described above, is not commensurate with the enablement provided in regard to the large number of polynucleotides of unknown structure and function encompassed by the claims. As indicated above, the only structure disclosed is that of SEQ ID NO: 3 and the only function disclosed, i.e. detection of chlorinated ethylene-decomposing bacteria, is only relevant to the 18 nucleotides set forth in SEQ ID NO: 3. No other function or structures as encompassed by the claims have been disclosed. No disclosure of the 10 nucleotides of SEQ ID NO: 3 required to detect chlorinated ethylene-decomposing bacteria has been provided either. No information as to which bases in the polynucleotide of SEQ ID NO: 3 can be deleted, substituted or inserted to create a 90% sequence homolog of the polynucleotide of SEQ ID NO: 3 which can be used to detect chlorinated ethylene-decomposing bacteria. Moreover, the polynucleotides encompassed by the claims have the potential of encoding proteins, for which there is no function disclosed.

Stackebrandt (Encyclopedia of Life Sciences, pages 1-7, 2001) teaches that in the vast majority of cases, the 16S rDNAs of intraspecies are 100% sequence identical (page 7, column 1, lines 16-18) and that even strains which share 99% sequence similarity at the rDNA level, only share less than 40% sequence similarity at the DNA level (page 6, column 2, last paragraph, page 7, column 1, lines 1-15). Since the ability to perform degradative reactions is determined by the DNA, organisms having rDNAs which are extremely similar may not be able to perform the same degradative reactions. Therefore, it is unclear as to how one of skill in the art can use the claimed polynucleotides to detect chlorinated ethylene-decomposing bacteria if no information

has been provided in regard to (1) which additional nucleotides should be present in a nucleic acid comprising the polynucleotide of SEQ ID NO: 3, a 90% sequence homolog of SEQ ID NO: 3, or 10 consecutive bases of SEQ ID NO: 3, to detect chlorinated ethylene-decomposing bacteria, (2) which 10 nucleotides of SEQ ID NO: 3 are specific to chlorinated ethylene-decomposing bacteria, and (3) which are the nucleotides of SEQ ID NO: 3 which can be modified such that a 90% homolog of the polynucleotide of SEQ ID NO: 3 can still be used to detect chlorinated ethylene-decomposing bacteria. In view of the lack of relevant examples, the amount of information provided, the lack of knowledge as to other functions for the claimed polynucleotides, and the state of the art in regard to the use of rDNA sequence similarity to identify species and/or phenotype, one of skill in the art would have to go through the burden of undue experimentation to determine (1) which of the nucleic acids encompassed by the claims can be used to detect chlorinated ethylene-decomposing bacteria, and (2) how to use those polynucleotides which cannot be used to detect chlorinated ethylene-decomposing bacteria. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Hendrickson et al. (WO 00/63443 10/26/2000; cited in the IDS). Hendrickson et al. teaches several polynucleotides (GenBank accession numbers AX039535, AX039537, AX039538, AX039539) corresponding to

16S rDNAs of chlorinating bacteria (Dehalococcoides ethenogenes) which comprise all of SEQ ID NO: 3. See attached alignments. Claim 1 is directed in part to a nucleic acid comprising the polynucleotide of SEQ ID NO: 3. Claim 2 is directed in part to a nucleic acid comprising at least 10 bases of the polynucleotide of SEQ ID NO: 3. Since the polynucleotides of Hendrickson et al. comprise all of SEQ ID NO: 3, they anticipate the claims as written. In addition, Hendrickson et al. teaches that the polynucleotides can be used to detect dechlorinating bacteria using nucleic acid hybridization or in PCR (page 12, last 2 lines, page 13, first 2 lines). Since, as known in the art, nucleic acid hybridization requires radioactive labeling of nucleotides, the polynucleotides of Hendrickson et al. are labeled probes. Claims 3-4 are directed to the nucleic acids of claims 1-2 wherein said nucleic acids have been labeled with a radioactive element, enzyme, fluorescence substance, antigen, antibody or chemical substance. As such, the teachings of Hendrickson et al. anticipate the claims as written.

19. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Miskin et al. (Microbiology 145:1977-1987, 1999; GenBank accession number AF093598). Miskin et al. teaches a polynucleotide which comprises all of SEQ ID NO: 3. See attached alignment. Claim 1 is directed in part to a nucleic acid comprising the polynucleotide of SEQ ID NO: 3. Claim 2 is directed in part to a nucleic acid comprising at least 10 bases of the polynucleotide of SEQ ID NO: 3. Since the polynucleotide of Miskin et al. comprises all of SEQ ID NO: 3, it anticipates the claims as written.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskin et al. (Microbiology 145:1977-1987, 1999; GenBank accession number AF093598). Miskin et al. have been discussed above. Miskin does not teach labeling of the polynucleotides.

Claims 3-4 are directed to the nucleic acids of claims 1-2, as described above, wherein said nucleic acids have been labeled with a radioactive element, enzyme, fluorescence substance, antigen, antibody or chemical substance.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to label the polynucleotide of Miskin et al. with a radioactive element, enzyme, fluorescent substance, antigen, antibody or chemical substance. A person of ordinary skill in the art is motivated to label the polynucleotide of Miskin et al. with a radioactive element, enzyme,

fluorescent substance, antigen, antibody or chemical substance for the benefit of using it as a probe in different types of detection assays. One of ordinary skill in the art has a reasonable expectation of success at labeling the polynucleotide of Miskin et al. since labeling polynucleotides to use them as probes is well known and widely used in the art. For example, use of a polynucleotide in a hybridization assay wherein the polynucleotide to be used as a probe is radioactively labeled is one of the most common assays in Molecular Biology. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Conclusion

23. No claim is in condition for allowance.

24. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

25. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 24, 2003

REBECCA E. PROUTY
PRIMARY EXAMINER